

REMARKS

Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested. Prior to entry of the present amendment, claims 9-24, 27 and 28 are pending and under consideration. By the present amendment, claims 12, 17 - 24, and 28 are canceled, and claims 9, 13, and 27 are amended to more specifically recite certain aspects of the invention. Support for these amendments may be found throughout the specification and claims as originally filed and does not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 12, 17, 20, and 27 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. More specifically, claim 12 allegedly lacks antecedent support in reciting, "the total cell count." In addition, claim 17 is allegedly unclear in its recitation of, "a value," lacks antecedent support in reciting, "the detected viable cell value," and is confusing regarding its correlation step. Claims 20 and 27 allegedly lack antecedent support in reciting, "the total cell count" and "the method," respectively. Also, claim 27 is allegedly indefinite in reciting "or other methods of counting," and confusing regarding the correlation of the instructions with means for determining cell counts.

Applicants traverse this basis of rejection and submit that the skilled artisan would clearly understand the metes and bounds of the claimed subject matter, particularly in light of the teachings of the instant specification. Nonetheless, without acquiescence to this basis of rejection, claims 12, 17, and 20 have been canceled, and claim 27 has been amended to provide antecedent basis for the method and remove reference to "other methods of counting viable cells," thereby obviating this basis of rejection. Accordingly, Applicants respectfully request that these bases of rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 9-12, 14, 15, 17-20, 22, and 23 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Breeuwer *et al.* Specifically, the Examiner alleges that Breeuwer *et al.* teaches a method for detecting cell viability by flow cytometry using fluorescein diacetate dye, which diffuses into or is translocated into cells, where it is detectably altered by esterase activity in viable cells.

Claims 9, 11, 12, 14, 16, 17, 19, 20, 22, 24, 27, and 28 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Sarkadi *et al.* The Examiner alleges that Sarkadi *et al.* disclose a method and kit for detecting viability of cells using a fluorometer and calcein AM dye, which is converted from a non-fluorescent form to a fluorescent form in viable cells.

Applicants respectfully traverse these bases of rejection and submit that neither reference anticipates the invention, since neither reference teaches each element of the instant claims. Without acquiescence to these bases of rejection and solely for the purposes of expediting prosecution of the instant application, claims 12, 17-20, 22-24, and 28 have been canceled, and claims 9 and 27 have been amended to more clearly describe a particular embodiment of the invention. Support for these amendments is provided throughout the application as filed, including, *e.g.*, on page 5, lines 15-25. Accordingly, the claims are now directed to embodiments of the invention relating to a method of determining the percent of viable cells in a sample, which includes determining both an amount of viable cells in the sample and a total amount of viable and non-viable cells in the sample. Applicants respectfully submit that neither reference teaches or suggests a method that involves determining both a number of viable cells and a number of total viable and non-viable cells. Rather, the methods described in Breeuwer *et al.* are directed to determining yeast viability, and those of Sarkadi *et al.* are directed to determining MDR activity and viability of cells. Neither reference describes a method of determining the percentage of viable cells within a sample. Accordingly, Applicants submit that these references fail to anticipate the instant claims. In light of the above amendments and remarks, Applicants respectfully request that these bases of rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 13 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Breeuwer *et al.* or Sarkadi *et al.* in view of Katz. More specifically, the Examiner concedes that neither Breeuwer *et al.* nor Sarkadi *et al.* teach using UV absorption to determine total cell count. However, the Examiner alleges that Katz discloses a method of detecting both viable and nonviable cells by contacting cells with a fluorescent dye, counting dead cells that fluoresce using a microscope, killing all cells using heat, and then determining the total count of cells by ultraviolet absorption. The Examiner alleges that it would have been obvious to incorporate the teachings of Katz related to determining counts of both viable and total cells using UV absorption measurements into a method of determining the amount of viable cells as taught by Breeuwer *et al.* or Sarkadi *et al.*

Applicants respectfully traverse this basis of rejection and submit that neither combination of references teaches each element of the claimed invention and, therefore, both combinations of references fail to establish a *prima facie* case of obviousness of the claimed invention. Without acquiescence to this basis of rejection, claim 21 has been canceled, and claim 13 has been amended to depend from claim 9. Accordingly, claim 13 now recites a method of determining the percentage of viable cells in a sample comprising determining an amount of viable cells using a dye that is detectably altered by enzymatic activity in viable cells and determining a total amount of viable cells using native UV absorption. As conceded by the Examiner, neither Breeuwer *et al.* nor Sarkadi *et al.* teach a method employing the measurement of native UV absorption. Applicants submit that Katz fails to remedy this deficiency, since Katz also fails to describe the measurement of native UV absorption to determine total cell count. Rather, the method described by Katz measures non-native UV absorption produced by staining dead cells with the UV detectable dye, SITS.

Applicants further submit that even assuming *arguendo* that the cited combinations of references described each element of the claimed invention, none of the references provide the requisite teaching or motivation to combine the references to achieve the claimed invention. Rather, Applicants submit that Katz actually teaches away from the claimed

invention. Applicants submit that the method described by Katz employs a single agent or means for measuring both total cells and non-viable cells, thereby determining the number of viable cells. It directly follows that the skilled artisan would see no reason or motivation to add an additional step of directly determining the number of viable cells using yet another reagent. Clearly, the skilled artisan would find this to be unnecessary and, in fact, redundant. Neither Breeuwer *et al.* nor Sardakai *et al.* provide such motivation, since they both teach methods related to determining the presence of viable cells, not the number of non-viable cells.

Applicants respectfully submit that the claims are patentable over the cited combinations of references, and respectfully request that this basis of rejection be withdrawn in light of the above amendments and remarks.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants submit that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. While every effort has been made to place this application in condition for allowance, should any remaining issues exist, the Examiner is requested to contact the undersigned at (206) 622-4900.

Respectfully submitted,

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